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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,126	07/23/2001	Padma S. Bagaria		2532
7590	06/09/2004			
TED MASTERS 23344 8TH STREET NEWHALL, CA 91321			EXAMINER NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER

1641

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/910,126	Applicant(s) BAGARIA, PADMA S.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/9/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 2, claims 10-16 in Paper dated 4/9/2004 is acknowledged.
2. Claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting human blood using labeled anti-Hb antibodies which are captured and detected, does not reasonably provide enablement for a labeled anti-Hb antibody in which the label is released from the antibody thereby providing a visual indication. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches conventional labels such as enzymes and particulate labels conjugated to antibodies to hemoglobin. The specification does not teach how these labels are conjugated to the antibodies such that binding of a complex comprising hemoglobin and

labeled antibody to an immobilized capture reagent allows the labels, i.e. enzymes, to be released from the antibodies thereby providing a visual indication. No example is given nor any other discussion of releasable labels is found. In conventional assays, binding of a labeled complex to the capture reagents localized the label in a detection area, and the addition of substrate for the enzyme label allows color to develop, thus detection is made. Or in the case of particulate direct labels, binding of the labeled complex localized the visual direct labels in the detection area enabling detection. Generally, neither labels such as enzymes nor particulate labels is released from the antibody. In instances where labels are released, a set of specific condition must be met before such labels are operable. Roberts, for examples, teaches the use of liposome-encapsulated labels in test strips. Roberts teaches that in order for the signal from the labels to be read, liposome lysing reagents must be employed. Without such lysing reagent, the label is not released from the liposome. See entire document.

Because the specification does not teach how skilled in the art may make and use releasable labels it would require undue experimentation to make and use the invention as claimed.

Claim Rejections - 35 USC § 112

4. Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 14 are vague and indefinite because it is unclear how releasing the labels from the antibodies provides a visual indication. It would appear that once the labels are

released from the antibodies, they are no longer localized in the detection zone and would therefore, migrate away from such zone, thus any color that developed would be lost.

Claims 10 and 14 also lacks a correlation between observation step and the preamble of the claim, i.e. does the observation of visual indications confirms the presence or absence of the human blood? Furthermore, these claims recite a step of depositing a test sample *containing human hemoglobin* or *containing no human hemoglobin*, and performing an assay to detect the presence or lack thereof of human hemoglobin in said test samples. If it is known prior to the assay that the sample contains human hemoglobin Hb antigen, as recited in claim 10, for example, why would it be necessary to perform the assay?

Claims 11 and 15 are vague and indefinite because it is unclear what the role of the IgM is. These claims recite that in addition to the immobilized antihuman Hb antibodies at the test station, the method *further* includes IgM at the test station. What role does this IgM have in the method?

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,221,678 discloses test devices and methods for the identification of analytes such as human and primate hemoglobins.

US 4,301,139 discloses specific binding assays and reagents appropriate for such assays including IgG, IgE, IgM and IgA.

US 5,958,791 discloses liposome based assays.

US 5,998,156 discloses assays for hemoglobins in less than 10 minutes.

US 5,932,480 discloses assays for hemoglobins.

US 6,319,676 discloses test devices for analytes.

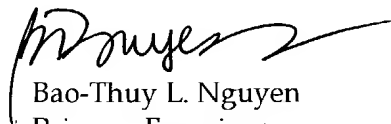
US 6,472,160 discloses immunoassay device for hemoglobins.

EP 0,291,194 discloses immunoassays and devices therefor.

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641